Crosswalk between NCQA and AAHRPP Standards
For Accreditation of Human Research Protection Programs

The new contract for accreditation of VA Human Research Protection Programs (HRPPs) has been awarded to The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) effective December 1, 2005.

The purpose of this crosswalk is to help VA facilities become familiar with the AAHRPP Accreditation Standards. The AAHRPP standards in this crosswalk were taken from AAHRPP Accreditation Standards (May 10, 2004). The NCQA standards in this crosswalk were taken from VAHRPAP Standards Version 2.1.

Some of the major differences between NCQA and AAHRPP include:

- AAHRPP has the flexibility to handle all configurations of VA HRPPs, including small research programs and regional IRBs. All configurations are eligible to apply for a full 3 years AAHRPP accreditation. There is no longer a requirement for at least 8 new protocols per year to become accredited.
- AAHRPP's site visit process provides a real time review of the HRPP and gives credit for recent program improvements. For example, AAHRPP will accept changes made after its site visit.
- AAHRPP does not have a 12-month look back period.
- AAHRPP provides a more comprehensive HRPP review including assessment of investigators and subjects, and it emphasizes continuous quality improvement.

There are many similarities between the NCQA and AAHRPP standards. The tables below are organized according to the AAHRPP standards, with the NCQA standards inserted where similarities exist. However, not all of the content within each box is necessarily equivalent. In some cases NCQA is more prescriptive (or specific in how to satisfy an element), while AAHRPP is more expansive (or considers a variety of methods to satisfy an element). While some of the NCQA standards do not directly or completely cross-over to the AAHRPP standards, they do provide a very strong foundation for the AAHRPP accreditation process.

A VA specific version of the AAHRPP Evaluation Instrument for Site Visitors is available on the AAHRPP website on page two of their Document Library. In this library, you will also find the AAHRPP procedures, standards, and application form. In the Education section of the AAHRPP website you will find several tip sheets designed to help facilities meet the AAHRPP accreditation standards. Quick links to these documents can be found in the AAHRPP section of the PRIDE website.

AAHRPP Standards	NCQA Standards
Domain I: Organization	
Standard I-1: The Organization has a systematic and comprehensive human research protection program with appropriate leadership.	
Element I.1.A: Tip Sheet The Organization has a written plan for its HRPP appropriate for the volume and nature of the research involving human participants conducted under its auspices.	**Element INR1A- Page 1** The institution ensures its compliance with VA and Federal regulations concerning the protection of human research subjects by: 1. maintaining a written assurance 2. identifying the official who is responsible for the assurance 3. documenting principles concerning the protection of human research subjects 4. documenting the organizational structure, process, roles and responsibilities for making policy to protect human research subjects 5. having an arrangement for an IRB registered with OHRP
Element I.1.B: The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.	
Element I.1.C: The Organization delegates responsibility for the HRPP to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.	**Element INR1B- Page 3** A designated committee or individual (e.g. R&D Committee, ACOS for R&D or R&D Coordinator) ensures that the human research protection program (HRPP) is operational. The following specific responsibilities must be documented and assigned: 1. implementation of the institution's HRPP policy 2. review and evaluation of the reports and results of compliance assessment and quality improvement activities (QA/QI) related to research 3. implementation of needed improvements and follow-up on actions, as appropriate 4. monitoring changes in VA and other Federal regulations and policies that relate to human research protections.
Element I.1.D: The Organization has and follows written policies and procedures for working with sponsors, investigators, research participants, and the Research Review Unit to uphold ethical standards and practices in research.	**Element INR1A- Page 1** The institution ensures its compliance with VA and Federal regulations concerning the protection of human research subjects by: 3. documenting principles concerning the protection of human research subjects 4. documenting the organizational structure, process, roles and responsibilities for making policy to protect human research subjects 5. having an arrangement for an IRB registered with OHRP.

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Standard I-2: The Organization assures the availability of resources sufficient to protect the rights and welfare of research participants, taking into consideration the research activities in which they are asked to participate.	
Element I.2.A: Tip Sheet The Organization provides resources to the HRPP sufficient for conducting the activities under its jurisdiction.	**Element INR1D- Page 5** The institution engages in a systematic budgeting process for the HRPP. When developing or evaluating the HRPP budget, the institution considers the following factors: 1. personnel 2. materials and supplies 3. space 4. capital equipment 5. training and education
Element I.2.B: Tip Sheet The Organization provides the appropriate number of IRBs for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner. …may use the IRBs of another organization to meet the needs of its research program.	**Element INR2A - Page 7** Prior to selection / designation of an external IRB, the institution evaluates the IRB's capacity to perform the designated activities. **Element INR2B- Page 9** If the institution uses a VAMC multi-site IRB or the IRB(s) of an affiliated university or another VA facility, there is a formal IRB agreement that includes, at a minimum: 1. specific requirements for the membership and operation of the IRB to review VA research, in compliance with VA regulations 2. the respective responsibilities for human subject protection of each institution and of the designated IRB 3. the scope of VA activities to be reviewed by the IRB 4. the method, frequency and nature of reporting to the R&D Committee 5. the process by which the institution evaluates the IRB's performance 6. the remedies available to the institution, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.
Element I.2.C: The Organization provides resources that are necessary for human research protection, care of research participants, and safety during the conduct of the research.	
Element I.2.D: The Organization provides for communication and interaction for its units that might be involved in the conduct of human research.	
Standard I-3: The Organization monitors compliance of all those involved in the research process.	

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Element I.3.A: The Organization has and follows written policies and procedures governing research with research participants that are available to investigators and research staff affiliated with the organization.	
Element I.3.B: Tip Sheet Tip Sheet The Organization has and follows written policies and procedures that allow the Research Review Unit to function independently of other organizational entities in its role in protecting research participants.	
Element I.3.C: Tip Sheet The Organization has and follows written policies and procedures for determining when studies meet the regulatory definitions of human research.	
Element I.3.D: Tip Sheet The Organization has and follows written policies and procedures for determining when studies are exempt from applicable federal, state, and local regulations and the Organization's policies and procedures. Such policies and procedures indicate that exemption determinations are not to be made by investigators or others who might have an apparent or real conflict of interest regarding the studies.	**Element IRB4C- Page 47** The institution has a documented process for determining exempt status that: 1. includes a definition of categories of research that are exempt from IRB review 2. includes a process for determining exempt status, including who, by title and position, may make exempt determination 3. has been in place for at least 12 months **Element IRB4D- Page 48** The institution or IRB makes determinations of exempt status in accordance with local and VA policy and Federal regulations including: 1. exempted research falls into an allowable category of research 2. the decision for exempt research is made by the authorized individual 3. the basis (allowable category) for making the exempt determinations is documented
Element I.3.E: Tip Sheet The Organization has and follows written policies and procedures for addressing protection of participants in research exempt from federal regulations.	
Element I.3.F: The Organization includes in its HRPP policies and procedures regarding the areas in which federal and state law differ, and provides guidance about regulatory compliance.	
Element I.3.G: Tip Sheet The Organization has and follows written policies and procedures to identify, manage, and minimize individual conflicts of interest of investigators. The Organization works with the IRB regarding conflicts of interest, when appropriate.	**Element INR3B- Page 13** The institution has a documented process for identification and management of conflicts of interest for investigators.
Element I.3.H: The Organization is developing written policies and procedures for recognizing and managing institutional conflicts of interest.	

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Element I.3.I: Tip Sheet The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with HRPP requirements.	
Element I.3.J: The Organization has and follows written policies and procedures for addressing unanticipated problems involving risks to research participants or others.	**Element IRB3B- Page 38** The institution has a documented process for review of interim reports and modifications of previously approved research that: 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects and if available, data safety monitoring reports **Element IRB3C- Page 40** The institution has a documented process for the conduct of continuing review that: 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects, and if available, data safety monitoring reports
Element I.3.K: The Organization maintains and supports an assurance of compliance that identifies how the organization protects research participants, when applicable.	
Element I.3.L: The Organization implements a plan to measure and improve HRPP effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws.	**Element INR5A- Page 20** The institution annually evaluates investigator compliance with HRPP and IRB requirements.
Element I.3.M: Tip Sheet The Organization has and follows written policies and procedures so that investigators may bring forward to the Organization concerns or suggestions regarding the HRPP, including the IRB review process.	
Standard I-4: The Organization ensures that all personnel reviewing, conducting, or supporting human research demonstrate and maintain sufficient knowledge of the ethical principles and federal, state, and local requirements for protecting research participants.	
Element I.4.A: The Organization evaluates and contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.	**Element INR6A Page 22** The institution sets requirements for education and training, including: 1. type and scope of human subject protection education and training that meets VA and Federal requirements 2. identification of individuals for whom education and training is required in compliance with VA and Federal requirements 3. methods for confirming that individuals required to have education and training by VA and Federal requirements have met training requirements.
Element I.4.B: The Organization has and follows written policies and procedures requiring	**Element INR6B Page 24** All required individuals have been educated and/or trained in Human Subject

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all individuals involved with the HRPP to understand and apply their obligation to protect the rights and welfare of research participants.	Protections in accordance with the institution's policies and procedures.
Standard I-5: The Organization has and follows written policies and procedures that use of any investigational or unlicensed test article complies with all federal, state, or local regulations.	
Element I.5.A: The Organization secures assurances from the sponsor that the manufacture and formulation of investigational or unlicensed test articles conform to federal regulations	
Element I.5.B: The Organization has policies and procedures to ensure that the handling of investigational or unlicensed test articles meets organizational standards relating to pharmacy, inventory control, and documentation.	**Element INR4A- Page 14** The institution has a documented process for handling investigational drugs, as required by Federal regulations, that addresses the following: 1. receipt 2. storage 3. security 4. dispensing 5. disposition of unused stock **Element INR4B- Page 16** The Pharmacy Service maintains an investigational drug log, which includes all information required by Federal regulation and policy: 1. name of drug 2. manufacturer or other source 3. date of receipt of the drug 4. quantity received 5. expiration date 6. control number 7. date protocol approved 8. name of authorized practitioner signing the prescription 9. name of the patient receiving the prescription 10. serial number of the prescription 11. quantity dispensed 12. balance remaining after the transaction **Element INR4C- Page 18** The Pharmacy Service ensures that investigational drugs are not dispensed without the following on file in the pharmacy: 1. approved protocol 2. signed informed consent form 3. VA Form 10-9012 (Investigational Drug Information Record) **Element INR4D- Page 19**

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	The institution has a documented process for the use of investigational devices that addresses the following: 1. storage 2. security 3. dispensing
Element I.5.C: The Organization has and follows written policies and procedures for compliance with federal regulations governing emergency use of an investigational or unlicensed test article.	**Element ICS3A- Page 92** The institution requires that, for each situation in which a test article is to be administered and informed consent may not feasibly be obtained, the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing and submit to the IRB within 5 working days all of the following: 1. the subject is confronted by a life-threatening situation necessitating the use of the test article 2. informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject 3. time is not sufficient to obtain consent from the subject's legal representative 4. there is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
Domain II: Research Review Unit, Including IRBs	
Standard II-1: The structure and composition of the Research Review Unit are appropriate to the amount and nature of the research reviewed.	
Element II.1.A: The Research Review Unit has and follows written policies and procedures requiring protocols to be reviewed by individuals with appropriate scientific or scholarly expertise.	**Element IRB2B- Page 35** The IRB has a documented process for assigning review responsibility consistent with protocol content and reviewer expertise.
Element II.1.B: The IRB has a process for obtaining additional expertise when reviewing a specific protocol.	**Element IRB1B- Page 31** This institution has a documented process that provides for the inclusion of individuals, either as consultants or permanent members, with competence in special areas, to assist in review of issues that require additional expertise.
Element II.1.C: Tip Sheet The Research Review Unit has and follows written policies and procedures so that IRB members and consultants do not participate in the review of protocols in which they have a conflict of interest, except to provide information requested by the IRB.	**Element INR3A- Page 12** The institution has a documented process to identify and manage conflict of interest of IRB members that: 1. defines conflict of interest 2. establishes rules of IRB-member declaration of conflicts 3. establishes processes for evaluating any conflict of interest 4. outlines preferred or allowable remedies to manage the conflict or

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	eliminate the conflicting interest 5. has been in place for at least 12 months.
Element II.1.D: Tip Sheet The IRB has a qualified IRB chair, members, and staff, whose membership and composition are periodically reviewed. The IRB administrator, staff, chair, and members have knowledge, skills, and abilities appropriate to their respective roles.	**Element INR2C- Page 11** The institution oversees its designated IRB(s) and documents consideration of the following: 1. for new Chairs (appointed within the look-back period), the institution assesses the qualifications and experience of the IRB Chair 2. that the IRB and the membership of the IRB are appropriate, given the research being reviewed 3. that the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research adequacy of the IRB's policies and procedures **Element IRB1A- Page 29** Consistent with VA and Federal regulations and policies, the IRB includes: 1. at least five members 2. at least one member whose primary area of interest is non-scientific 3. at least one member whose primary area of interest is scientific 4. members of more than one profession 5. at least one member who is not otherwise affiliated with the VA or affiliated university HRPP and who is not part of the immediate family of a person affiliated with either organization 6. diversity of membership based on consideration of race, gender and cultural background 7. if an affiliated university IRB, at least one member who is a VA representative 8. if a VA IRB, a Chair with a VA appointment 9. if a VA IRB, at least one member from the R&D Committee
Element II.1.E: Tip Sheet The IRB membership roster includes sufficient information about members to permit appropriate representation at the meeting for each protocol under review. One or more unaffiliated members are represented on the IRB and one or more members can represent the general perspective of participants.	**Element IRB1A- Page 29** Consistent with VA and Federal regulations and policies, the IRB includes: 1. at least five members 2. at least one member whose primary area of interest is non-scientific 3. at least one member whose primary area of interest is scientific 4. members of more than one profession 5. at least one member who is not otherwise affiliated with the VA or affiliated university HRPP and who is not part of the immediate family of a person affiliated with either organization 6. diversity of membership based on consideration of race, gender and cultural background 7. if an affiliated university IRB, at least one member who is a VA representative 8. if a VA IRB, a Chair with a VA appointment

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	9. if a VA IRB, at least one member from the R&D Committee
Element II.1.F: The IRB meets regularly and members have sufficient time to review materials prior to meeting.	
Standard II-2: The Research Review Unit systematically evaluates each research study to ensure the protection of participants.	
Element II.2.A The Research Review Unit has and follows written policies and procedures for conducting initial and continuing review, and procedures for handling modifications to research studies.	**Element IRB3B- Page 38** The institution has a documented process for review of interim reports and modifications of previously approved research that: 1. requires IRB consideration of changes to the research 2. requires IRB consideration of adverse event reports 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects and if available, data safety monitoring reports 4. includes IRB consideration of protocol violations and/or deviations 5. includes IRB consideration of investigator compliance 6. has been in place for at least 12 months **Element IRB3C- Page 40** The institution has a documented process for the conduct of continuing review that: 1. includes IRB consideration of changes to the research, protocol deviations and violations, since the last scheduled (continuing or initial) review 2. includes IRB consideration of adverse event reports 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects, and if available, data safety monitoring reports 4. includes IRB consideration of investigator compliance 5. includes IRB management of protocols with lapsed approval 6. has been in place at least 12 months **Element CRB1A- Page 57** The institution has a documented process for initial and continuing review that: 1. requires the IRB to evaluate risks to subjects 2. requires the IRB to determine whether risks have been minimized 3. requires the IRB to evaluate the anticipated benefits 4. requires the IRB to determine whether risks to subjects are reasonable in relation to expected benefits 5. requires the IRB to determine the interval for continuing review based on the level of risk 6. has been in place for at least 12 months

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	Element CRB4B- Page 70 The IRB documents its review of the following sources of information about risks and benefits at scheduled continuing review: 1. serious adverse event reports 2. amended or updated Investigator's Brochures 3. new information available regarding the research project that may change the risk/benefit ratio 4. research findings to date, including summary of subject experiences (benefits, adverse reactions) 5. summary of safety monitoring reports 6. unanticipated problems involving risks to subjects 7. enumeration of subjects withdrawn, and the reasons for withdrawal
Element II.2.B: The Research Review Unit has and follows written policies and procedures to conduct reviews by the expedited procedure.	**Element IRB4A- Page 43** The institution has a documented process for expedited review that: 1. defines criteria for the qualifications and experience of an IRB member to serve as the Chair's designee for conducting expedited review 2. includes criteria for determining that research involves no more than minimal risk 3. includes criteria for determining that changes in previously approved research during the period for which the approval is authorized are minor 4. includes methods for advising IRB members of research approved through expedited review 5. includes conditions under which the IRB permits expedited review at continuing review 6. has been in place for at least 12 months **Element IRB4B- Page 45** The IRB conducts expedited review of protocols in conformance with its policies and procedures including: 1. the IRB Chairperson or designee conducts expedited review 2. all IRB members are notified of all expedited reviews 3. expedited reviews meet regulatory requirements for use of expedited procedure 4. the IRB documents the basis for allowing expedited review
Element II.2.C: The Research Review Unit receives and reviews the relevant information to evaluate research studies during initial review.	**Element IRB2A- Page 32** The institution has a documented process that requires IRB members or primary reviewers to receive the following at initial review: 1. protocol 2. informed consent form, or request of waiver 3. any relevant merit reviews or grant applications 4. Investigator's Brochure or equivalent material 5. advertisements or other materials provided to subjects

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	6. subject surveys or questionnaires **Element CRB6A- Page 75** The institution has a documented process for evaluating protocols regarding equitable selection of subjects that: 1. requires IRB consideration of the purposes of the research 2. requires IRB consideration of the setting in which the research occurs 3. requires IRB consideration of the scientific and ethical reasons for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons 4. requires IRB consideration of the scientific and ethical reasons for excluding classes of persons who might benefit from the research 5. has been in place for at least 12 months **Element CRB6B- Page 77** The IRB obtains the following information to support its evaluation of whether subject selection criteria are equitable and fairly distribute the burdens, risks and benefits of research: 1. purpose of the research 2. setting in which the research occurs 3. scientific and ethical justification for excluding classes of persons who might benefit from the research 4. inclusion criteria 5. exclusion criteria
Element II.2.D: The Research Review Unit receives and considers relevant information to conduct continuing reviews of research studies and, when appropriate, requests changes.	**Element IRB3B- Page 38** The institution has a documented process for review of interim reports and modifications of previously approved research that: 1. requires IRB consideration of changes to the research 2. requires IRB consideration of adverse event reports 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects and if available, data safety monitoring reports 4. includes IRB consideration of protocol violations and/or deviations 5. includes IRB consideration of investigator compliance 6. has been in place for at least 12 months **Element IRB3C- Page 40** The institution has a documented process for the conduct of continuing review that: 1. includes IRB consideration of changes to the research, protocol deviations and violations, since the last scheduled (continuing or initial) review 2. includes IRB consideration of adverse event reports 3. requires IRB consideration of reports of unanticipated problems involving

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	risk to subjects, and if available, data safety monitoring reports 4. includes IRB consideration of investigator compliance 5. includes IRB management of protocols with lapsed approval 6. has been in place at least 12 months **Element IRB3D- Page 42** The IRB conducts continuing review within the determined approval period or studies are not allowed to continue. **Element CRB4B- Page 70** The IRB documents its review of the following sources of information about risks and benefits at scheduled continuing review: 1. serious adverse event reports 2. amended or updated Investigator's Brochures 3. new information available regarding the research project that may change the risk/benefit ratio 4. research findings to date, including summary of subject experiences (benefits, adverse reactions) 5. summary of safety monitoring reports 6. unanticipated problems involving risks to subjects **Element CRB6C- Page 78** The IRB obtains the following information at continuing review to support its evaluation of whether recruitment methods, enrollment procedures and selection criteria fairly distribute the burdens, risks and benefits of research: 1. number of subjects entered into the study 2. gender of subjects entered into the study
Element II.2.E: The Research Review Unit receives and considers the relevant information to evaluate proposed amendments to research studies.	**Element IRB3B- Page 38** The institution has a documented process for review of interim reports and modifications of previously approved research that: 1. requires IRB consideration of changes to the research 2. requires IRB consideration of adverse event reports 3. requires IRB consideration of reports of unanticipated problems involving risk to subjects and if available, data safety monitoring reports 4. includes IRB consideration of protocol violations and/or deviations 5. includes IRB consideration of investigator compliance 6. has been in place for at least 12 months
Standard II-3: The Research Review Unit maintains documentation of its activities.	
Element II.3.A: The Research Review Unit maintains a complete set of materials relevant	**Element INR1E- Page 6** The institution has accurate and complete records that indicate the following for

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to review of the research study in each protocol file.	each active research protocol: 1. date of original IRB approval 2. date of original R&D committee approval 3. date of most recent IRB approval 4. date by which next IRB continuing review must occur **Element IRB5B - Page 53** IRB decisions are reported to appropriate individuals: 1. all decisions about a research protocol are reported to the principal investigator 2. all decisions are reported to the R&D Committee 3. terminations and suspensions are reported to institutional officials responsible for the assurance and HRPP 4. terminations and suspensions are reported to the appropriate VACO officials, Federal agencies or departments
Element II.3.B: The Research Review Unit retains required records for a period of time sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies and procedures.	**Element IRB5C- Page 55** The IRB maintains and retains records in accordance with Federal requirements as follows: 1. records are retained for a minimum of three years following the completion of the study, or as required by sponsors 2. records are accessible for inspection and copying by authorized representatives of VA and other Federal regulatory agencies at reasonable times and in a reasonable manner 3. records are maintained and/or stored in a secure manner to protect the confidentiality of subject information
Element II.3.C: The IRB documents pertinent discussions and decisions on research studies and activities.	**Element CRB2D- Page 65** The IRB documents the following: 1. its consideration of the risks of research 2. its consideration of the impact of study design on risk 3. its consideration of provisions for safety monitoring 4. its determination that risks have been minimized to the extent possible 5. its determination of the risk level of the investigational devices **Element IRB5A- Page 51** Minutes of IRB meetings contain sufficient detail to show: 1. attendance 2. actions taken by the IRB at the meeting 3. the number of members voting for, against and abstaining on each action 4. the required quorum was present for the vote, including a non-scientific member 5. summary of the discussion of controverted issues and their resolution 6. members did not participate in the deliberations or voting on matters in

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	which they had conflicts of interest
Standard II-4: The Research Review Unit systematically evaluates risks to participants and potential benefits as part of the initial review and ongoing review of research.	
Element II.4.A: The Research Review Unit has and follows written polices and procedures for identifying and analyzing potential sources of risk and measures to minimize risk, including physical, psychological, social, legal, or economic risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to potential benefits to participants and to society.	**Element CRB1A- Page 57** The institution has a documented process for initial and continuing review that: 1. requires the IRB to evaluate risks to subjects 2. requires the IRB to determine whether risks have been minimized 3. requires the IRB to evaluate the anticipated benefits 4. requires the IRB to determine whether risks to subjects are reasonable in relation to expected benefits 5. requires the IRB to determine the interval for continuing review based on the level of risk 6. has been in place for at least 12 months **Element CRB2A- Page 59** The IRB obtains the following information to support its evaluation of risks to subjects: 1. identification of risks that may result from the research 2. the steps taken to minimize risk **Element CRB3A- Page 68** The IRB obtains the following information to support its evaluation of benefits of research: 1. the anticipated benefits of the research to research subjects 2. the importance of the knowledge that may be reasonably expected to result from research. **Element CRB4A- Page 69** The IRB documents its approval of research on the basis that risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, and the importance of the knowledge that may be expected to result from research.
Element II.4.B: Tip Sheet The Research Review Unit reviews the plan for data and safety monitoring in research protocols, when applicable, and determines that the plan provides adequate protection for participants.	**Element CRB2B- Page 62** The IRB obtains the following information to support its evaluation of sources and mitigators of risk: 1. study design 2. provisions for safety monitoring **Element CRB2D- Page 65** The IRB documents the following: 1. its consideration of the risks of research 2. its consideration of the impact of study design on risk 3. its consideration of provisions for safety monitoring 4. its determination that risks have been minimized to the extent possible

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	5. its determination of the risk level of the investigational devices
Element II.4.C: The Research Review Unit has and follows written policies and procedures for determining the risks to vulnerable populations as defined in applicable federal regulations, and specifically for determining the required risk categories in protocols involving children and prisoners.	**Element CRB2C- Page 63** For protocols that identify the potential for enrolling subjects who could be vulnerable to coercion or undue influence, the IRB obtains the following information about the inclusion of vulnerable subjects: 1. reasons for including vulnerable subjects in the research 2. additional safeguards included to protect the rights and welfare of vulnerable subjects **Element CRB2E- Page 66** For proposals that identify the potential for enrolling subjects who could be vulnerable to coercion or undue influence, the IRB documents its consideration of: 1. reasons for including vulnerable subjects in the research 2. additional safeguards included to protect the rights and welfare of vulnerable subjects.
Element II.4.D: Tip Sheet The Research Review Unit has and follows written policies and procedures for suspending or terminating previously approved research if warranted by findings in the continuing review or monitoring process.	
Standard II-5: The Research Review Unit systematically evaluates recruitment and participant selection practices.	
Element II.5.A: The Research Review Unit has and follows written policies and procedures to evaluate the equitable selection of participants from various populations and sub-populations, when applicable, and considers whether inclusion and exclusion criteria impose fair and equitable burdens and benefits.	**Element CRB2E- Page 66** For proposals that identify the potential for enrolling subjects who could be vulnerable to coercion or undue influence, the IRB documents its consideration of: 1. reasons for including vulnerable subjects in the research 2. additional safeguards included to protect the rights and welfare of vulnerable subjects. **Element CRB5B- Page 74** The IRB obtains the following information to support its evaluation of proposed subject recruitment methods: 1. the nature of the compensation offered to subjects for participation in research 2. proposed advertisements and other recruitment methods 3. methods used to identify and recruit potential subjects **Element CRB6A- Page 75** The institution has a documented process for evaluating protocols regarding equitable selection of subjects that: 1. requires IRB consideration of the purposes of the research

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	2. requires IRB consideration of the setting in which the research occurs 3. requires IRB consideration of the scientific and ethical reasons for including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons 4. requires IRB consideration of the scientific and ethical reasons for excluding classes of persons who might benefit from the research 5. has been in place for at least 12 months **Element CRB6B- Page 77** The IRB obtains the following information to support its evaluation of whether subject selection criteria are equitable and fairly distribute the burdens, risks and benefits of research: 1. purpose of the research 2. setting in which the research occurs 3. scientific and ethical justification for excluding classes of persons who might benefit from the research 4. inclusion criteria 5. exclusion criteria **Element CRB6C- Page 78** The IRB obtains the following information at continuing review to support its evaluation of whether recruitment methods, enrollment procedures and selection criteria fairly distribute the burdens, risks and benefits of research: 1. number of subjects entered into the study 2. gender of subjects entered into the study
Element II.5.B: The Research Review Unit reviews proposed participant recruitment methods, advertising materials, and participant payment arrangements, and permits them when fair, honest, and appropriate.	**Element ICS1C- Page 88** IRB-approved consent forms: 1. include information concerning the amount of payment to subjects 2. include information concerning the schedule of payments to subjects 3. do not include any exculpatory language through which the subject or the subject's legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence
Standard II-6: The Research Review Unit systematically evaluates the protection of privacy interests of research participants and the confidentiality of data in proposed research.	
Element II.6.A: Tip Sheet The Research Review Unit has written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research	**Element CRB7A- Page 79** The institution has a documented process for assessing whether there are adequate provisions to protect subject privacy and maintain confidentiality that:

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participants during and after their involvement in the research.	1. requires evaluation of methods used to obtain information about subjects 2. requires evaluation of methods used to obtain information about individuals who may be recruited to participate in studies 3. requires evaluation of the use of personally identifiable records 4. requires evaluation of methods to protect the confidentiality of research data 5. specifies when a Federal Certificate of Confidentiality should be obtained 6. has been in place for at least 12 months **Element CRB7B- Page 81** The IRB obtains the following information on the plan to protect the privacy and confidentiality of research subjects: 1. methods used to obtain information about participants 2. provisions for protecting the confidentiality of research data **Element CRB7C- Page 83** The IRB documents its evaluation of plans to protect the privacy and confidentiality of research subjects including the: 1. methods used to obtain information about participants 2. provisions for protecting the confidentiality of research data
Element II.6.B: Tip Sheet The Research Review Unit has written policies and procedures to evaluate proposed arrangements for protecting the confidentiality of identifiable data, when appropriate, during and after the conclusion of the investigation.	**Element CRB7A- Page 79** The institution has a documented process for assessing whether there are adequate provisions to protect subject privacy and maintain confidentiality that: 1. requires evaluation of methods used to obtain information about subjects 2. requires evaluation of methods used to obtain information about individuals who may be recruited to participate in studies 3. requires evaluation of the use of personally identifiable records 4. requires evaluation of methods to protect the confidentiality of research data 5. specifies when a Federal Certificate of Confidentiality should be obtained 6. has been in place for at least 12 months **Element CRB7B- Page 81** The IRB obtains the following information on the plan to protect the privacy and confidentiality of research subjects: 1. methods used to obtain information about participants 2. provisions for protecting the confidentiality of research data
Standard II-7: The Research Review Unit has and follows written policies and procedures that require informed consent to be solicited from participants or their legally authorized representatives, and it verifies that this requirement is met.	
Element II.7.A: The Research Review Unit evaluates compliance with policies and	**Element INR6C- Page 25** The institution's guidance to investigators for the process of informed consent:

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procedures on seeking informed consent from participants or their legally authorized representatives, and assent, when possible, from participants who cannot give consent.	1. states that the IRB has the authority to observe the consent process 2. states when the assessment of the subject's capacity to consent to a research protocol is required 3. identifies who, under VA policy, state and local law, may serve as a legally authorized representative for subjects determined to be incapable of making an autonomous decision 4. identifies who is eligible to inform the prospective subject about all aspects of the trial 5. identifies who is eligible to conduct the informed consent process 6. states that investigators must obtain consent prior to entering a subject into a study and or conducting any procedures required by the protocol, unless consent is waived by the IRB 7. includes processes for ensuring that information is given to the subject, or their legally authorized representative, in a language that is understandable to the subject or representative 8. provides for the prospective subject or the legally authorized representative to have sufficient opportunity to consider whether or not to participate 9. states that subjects must give consent without coercion or undue influence 10. has been in place for at least 12 months **Element INR6D- Page 27** The institution's guidance on informed consent forms: 1. states that the informed consent form must be the VA Form 10-1086, approved by the IRB and signed by the subject or the subject's legally authorized representative, except in cases where the documentation of informed consent is waived by the IRB 2. states that the consent form includes all basic elements of information as set forth in VA and other Federal regulations 3. states that the consent form includes appropriate additional elements of information as set forth in VA and other Federal regulations 4. states that all information concerning payment to subjects, including the amount and schedule of payments, be included in the consent form 5. states that no informed consent, whether oral or written, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence 6. states that the content of consent forms must be consistent with state laws regarding content 7. requires that information be given to the subject, or the subject's legally authorized representative, in a language that is understandable to the

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	subject or representative 8. has been in place for at least 12 months
Element II.7.B: The Research Review Unit has and follows written policies and procedures requiring that prospective participants whose decision-making capacity is in question be appropriately protected.	Element INR6C- Page 25 The institution's guidance to investigators for the process of informed consent: 2. states when the assessment of the subject's capacity to consent to a research protocol is required 3. identifies who, under VA policy, state and local law, may serve as a legally authorized representative for subjects determined to be incapable of making an autonomous decision 7. includes processes for ensuring that information is given to the subject, or their legally authorized representative, in a language that is understandable to the subject or representative 8. provides for the prospective subject or the legally authorized representative to have sufficient opportunity to consider whether or not to participate Element INR6D- Page 27 3. identifies who, under VA policy, state and local law, may serve as a legally authorized representative for subjects determined to be incapable of making an autonomous decision
Element II.7.C: The Research Review Unit reviews the content of the consent process, including the consent document, and the process through which informed consent is obtained from each participant, focusing on measures to improve participant understanding and voluntary decision-making.	**Element ICS1A- Page 84** IRB approved research protocols have consent forms that include all the basic elements of information as set forth in VA and other Federal regulations, or documentation of the basis for allowing an exception to or waiving the requirement for consent or any element of consent. Each consent form contains: 1. a statement that the study involves research 2. an explanation of the purposes of the research 3. the expected duration of the subject's participation 4. a description of the procedures to be followed 5. identification of any experimental procedures 6. a description of any reasonably foreseeable risks or discomforts to the subject 7. a description of any benefits to the subject or to others, which may reasonably be expected from research 8. a disclosure of appropriate alternative procedures or courses of treatment (if any) that might be advantageous to the subject 9. a statement describing the extent (if any) to which confidentiality of records identifying the subject will be maintained 10. a statement that the FDA may inspect the records 11. for research involving more than minimal risk, an explanation as to whether any compensation exists if injury occurs 12. for research involving more than minimal risk, an explanation as to

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	whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained and an explanation of whom to contact in the event or a research-related injury to the subject 13. an explanation of whom to contact for answers to pertinent questions about research and research subjects' rights 14. a statement that participation is voluntary 15. a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled 16. a statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled **Element ICS1C- Page 88** IRB-approved consent forms: 1. include information concerning the amount of payment to subjects 2. include information concerning the schedule of payments to subjects 3. do not include any exculpatory language through which the subject or the subject's legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence
Element II.7.D: The Research Review Unit has and follows written policies and procedures requiring that the investigator has and follows a procedure for properly documenting informed consent.	**Element INR6D- Page 27** The institution's guidance on informed consent forms: 1. states that the informed consent form must be the VA Form 10-1086, approved by the IRB and signed by the subject or the subject's legally authorized representative, except in cases where the documentation of informed consent is waived by the IRB 2. states that the consent form includes all basic elements of information as set forth in VA and other Federal regulations 3. states that the consent form includes appropriate additional elements of information as set forth in VA and other Federal regulations 4. states that all information concerning payment to subjects, including the amount and schedule of payments, be included in the consent form 5. states that no informed consent, whether oral or written, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence 6. states that the content of consent forms must be consistent with state laws regarding content 7. requires that information be given to the subject, or the subject's legally authorized representative, in a language that is understandable to the

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	subject or representative 8. has been in place for at least 12 months
Element II.7.E: The Research Review Unit has and follows written policies and procedures for approving waiver or alteration of the consent process and the waiver of consent documentation.	**Element ICS2A- Page 90** The institution has a documented process for documentation of informed consent that: 1. includes conditions under which the IRB may waive the requirement to obtain consent in accordance with VA and Federal regulations 2. includes conditions under which the IRB may permit waiver or alteration of any element of informed consent 3. includes conditions, if any, under which waivers of documentation of informed consent are allowed in accordance with VA and Federal regulations 4. the conditions under which a "short form" informed consent may be used 5. has been in place for at least 12 months
Element II.7.F: The Research Review Unit has and follows written policies and procedures for making exceptions to informed consent requirements in protocols for emergency situations, and appropriately reviews such protocols.	**Element ICS1A- Page 84** IRB approved research protocols have consent forms that include all the basic elements of information as set forth in VA and other Federal regulations, or documentation of the basis for allowing an exception to or waiving the requirement for consent or any element of consent. **Element ICS3A- Page 92** The institution requires that, for each situation in which a test article is to be administered and informed consent may not feasibly be obtained, the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing and submit to the IRB within 5 working days all of the following: 1. the subject is confronted by a life-threatening situation necessitating the use of the test article 2. informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject 3. time is not sufficient to obtain consent from the subject's legal representative 4. there is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject
Element II.7.G: The Research Review Unit has procedures for observation of the informed consent process in ongoing research, when appropriate.	**Element INR6C- Page 25** The institution's guidance to investigators for the process of informed consent: 1. states that the IRB has the authority to observe the consent process 2. states when the assessment of the subject's capacity to consent to a research protocol is required 3. identifies who, under VA policy, state and local law, may serve as a

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	legally authorized representative for subjects determined to be incapable of making an autonomous decision 4. identifies who is eligible to inform the prospective subject about all aspects of the trial 5. identifies who is eligible to conduct the informed consent process 6. states that investigators must obtain consent prior to entering a subject into a study and or conducting any procedures required by the protocol, unless consent is waived by the IRB 7. includes processes for ensuring that information is given to the subject, or their legally authorized representative, in a language that is understandable to the subject or representative 8. provides for the prospective subject or the legally authorized representative to have sufficient opportunity to consider whether or not to participate 9. states that subjects must give consent without coercion or undue influence 10. has been in place for at least 12 months
Standard II-8: The Research Review Unit has procedures for review and oversight of research conducted at multiple sites.	
Element II.8.A: The Research Review Unit has and follows policies and procedures for communication among IRBs, when appropriate, for research conducted at multiple sites (e.g., multi-site clinical trials, epidemiological studies, or educational surveys).	
Element II.8.B: The Research Review Unit has and follows policies and procedures for management of information obtained in multi-site research that may be relevant to the protection of research participants, such as reporting of unexpected problems or interim results.	
Domain III: Investigator	
Standard III-1: The organization used policies, procedures, and education programs to help its investigators carry out research studies ethically. In addition to following applicable federal, state, and local regulations, investigators follow ethical principles and standards appropriate for their discipline. In designing and conducting clinical trials, investigators follow Good Clinical Practice guidelines defined by the Food and Drug Administration. In designing and conducting research studies, Investigators have the protection of the rights and welfare of research participants as their primary concern.	

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Element III.1.A: Tip Sheet The Investigator and research staff consider conflicts of interest that might affect the relationship with the participant or the outcomes of the research, and with the organization, identifies and manages them.	**Element INR3B- Page 13** The institution has a documented process for identification and management of conflicts of interest for investigators.
Element III.1.B: The Investigator employs sound study design in accordance with the standards of the discipline and implements reporting mechanisms that provide information relevant to monitoring the rights and welfare of participants enrolled in the research.	**Element IRB3A- Page 36** The institution has a documented process to identify investigator responsibilities that: 1. includes submitting proposed research for approval (or exemption from IRB review) 2. includes submitting proposed changes in research for approval 3. includes submitting proposed changes in consent forms for approval 4. includes reporting deviations from approved protocol or other regulations and policies 5. includes reporting adverse events 6. includes reporting unanticipated problems involving risks to subjects 7. includes reporting required data for continuing review to the IRB 8. includes reporting changes made to eliminate apparent immediate hazards to subjects 9. includes notification of termination or completion of project 10. includes identifying a qualified clinician to be responsible for all study-related healthcare decisions 11. has been in place for at least 12 months
Element III.1.C: In research involving greater than minimal risk to participants, the Investigator provides the IRB with an evaluation of less risky alternatives, if any, and with plans for detecting harm promptly and mitigating potential injuries.	**Element IRB3A- Page 36** The institution has a documented process to identify investigator responsibilities that: 1. includes submitting proposed research for approval (or exemption from IRB review) 2. includes submitting proposed changes in research for approval 3. includes submitting proposed changes in consent forms for approval 4. includes reporting deviations from approved protocol or other regulations and policies 5. includes reporting adverse events 6. includes reporting unanticipated problems involving risks to subjects 7. includes reporting required data for continuing review to the IRB 8. includes reporting changes made to eliminate apparent immediate hazards to subjects 9. includes notification of termination or completion of project 10. includes identifying a qualified clinician to be responsible for all study-related healthcare decisions 11. has been in place for at least 12 months **Element CRB2A- Page 59** The IRB obtains the following information to support its evaluation of risks to

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	subjects: 1. identification of risks that may result from the research 2. the steps taken to minimize risk **Element CRB2B- Page 62** The IRB obtains the following information to support its evaluation of sources and mitigators of risk: 1. study design 2. provisions for safety monitoring
Element III.1.D: The Investigator or research staff recruits participants in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the risks to them.	**Element CRB2C- Page 63** For protocols that identify the potential for enrolling subjects who could be vulnerable to coercion or undue influence, the IRB obtains the following information about the inclusion of vulnerable subjects: 1. reasons for including vulnerable subjects in the research 2. additional safeguards included to protect the rights and welfare of vulnerable subjects
Element III.1.E: The Investigator conducting a research study involving human participants must document in the protocol that there are adequate resources and facilities to carry out the research.	
Element III.1.F: The Investigator develops an informed consent process and method of documentation appropriate to the type of research and the study population, emphasizing the importance of participant comprehension and voluntary participation.	**Element INR6C- Page 25** The institution's guidance to investigators for the process of informed consent: 1. states that the IRB has the authority to observe the consent process 2. states when the assessment of the subject's capacity to consent to a research protocol is required 3. identifies who, under VA policy, state and local law, may serve as a legally authorized representative for subjects determined to be incapable of making an autonomous decision 4. identifies who is eligible to inform the prospective subject about all aspects of the trial 5. identifies who is eligible to conduct the informed consent process 6. states that investigators must obtain consent prior to entering a subject into a study and or conducting any procedures required by the protocol, unless consent is waived by the IRB 7. includes processes for ensuring that information is given to the subject, or their legally authorized representative, in a language that is understandable to the subject or representative 8. provides for the prospective subject or the legally authorized representative to have sufficient opportunity to consider whether or not to participate 9. states that subjects must give consent without coercion or undue influence 10. has been in place for at least 12 months

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Element III.1.G: The Investigator and research staff respond to participants' complaints or requests for information.	**Element INR1C- Page 4** The institution has a documented process for responding to research-related complaints and allegations of noncompliance with institutional policies related to the HRPP that: 1. ensures a response to each complaint or allegation 2. requires investigation of complaints and allegations 3. establishes remedial action for and consequences of findings of noncompliance with HRPP and IRB policies 4. includes a process for reporting to institutional officials and other appropriate parties and authorities 5. has been in place for at least 12 months
Standard III-2: Investigators meet requirements for conducting research with human participants and comply with all applicable federal, state, and local regulations and the organization's policies and procedures for protecting research participants.	
Element III.2.A: Tip Sheet Investigators and research staff are qualified by training and experience for their research role, including knowledge of applicable federal, state, and local regulations; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants. Investigators understand the definition of human research and seek guidance when appropriate.	**Element INR6B- Page 24** All required individuals have been educated and/or trained in Human Subject Protections in accordance with the institution's policies and procedures. 1. All investigators have been educated and/or trained in Human Subject Protections in accordance with the institution's policies and procedures 2. All other individuals have been educated and/or trained in Human Subject Protections in accordance with the institution's policies and procedures
Element III.2.B: Investigators assess and report unanticipated problems occurring during a research study in accordance with applicable federal, state, and local regulations, and the organization's policies and procedures.	
Element III.2.C: Principal Investigators maintain appropriate oversight of their research protocols and research staff including recruitment, selection of study participants, and study conduct, and appropriately delegate research responsibilities.	
Element III.2.D: Tip Sheet The Investigator designs and carries out research studies with adequate data and safety monitoring during the research, when appropriate.	
Domain IV: Sponsored Research	
Standard IV-1: The organization applies its Human Research Protection Program to all sponsored research.	

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Element IV.1.A: The organization has a written agreement with the sponsor that the organization will use procedures that protect research participants.	
Element IV.1.B: The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury.	
Standard IV-2: Before the initiation of the research study, investigators or the organization arrange for the timely communication of information with sponsors that might affect the ongoing oversight of a protocol by the IRB.	
Element IV.2.A: In studies where sponsors bear responsibility for monitoring of the research, the organization has a written plan with the sponsor that the sponsor promptly reports to the organization findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.	
Standard IV-3: The organization works with sponsors to ensure that the benefits of knowledge obtained through research are realized and that the interests of current and future research participants are protected.	
Element IV.3.A: Before initiating research, the organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that investigators and sponsors will play in publication or disclosure of results.	
Element IV.3.B: When participant safety or medical care could be directly affected by study results, the organization addresses in the written agreement with the sponsor how results will be communicated to study participants.	
Domain V: Participant Outreach	
Standard V-1: The organization responds to the concerns of research participants.	
Element V.1.A: The organization has and follows written policies and procedures that require each protocol to provide a procedure for research participants to ask questions and voice concerns or complaints to the investigator.	**Element INR1C- Page 4** The institution has a documented process for responding to research-related complaints and allegations of noncompliance with institutional policies related to the HRPP that: 1. ensures a response to each complaint or allegation

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	2. requires investigation of complaints and allegations 3. establishes remedial action for and consequences of findings of noncompliance with HRPP and IRB policies 4. includes a process for reporting to institutional officials and other appropriate parties and authorities 5. has been in place for at least 12 months
Element V.1.B: The organization has and follows written polices and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol.	**Element INR1C- Page 4** The institution has a documented process for responding to research-related complaints and allegations of noncompliance with institutional policies related to the HRPP that: 1. ensures a response to each complaint or allegation 2. requires investigation of complaints and allegations 3. establishes remedial action for and consequences of findings of noncompliance with HRPP and IRB policies 4. includes a process for reporting to institutional officials and other appropriate parties and authorities 5. has been in place for at least 12 months
Standard V-2: The organization offers educational opportunities to participants, prospective participants, or their communities to enhance their understanding of research involving human participants.	
Element V.2.A: The organization conducts activities (e.g., distribution of pamphlets, public relations, or community speaking engagements) designed to enhance understanding of human research by participants, prospective participants, or their community, when appropriate.	
Element V.2.B: Tip Sheet The organization periodically evaluates its outreach activities and makes changes when appropriate.	